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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-0020; Docket No. CDC-2019-0109]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Coal Workers' Health Surveillance Program (CWHSP). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments (the Act).

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0109 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP),
(OMB Control No. 0920-0020, Exp. 09/30/2021) - Revision -
National Institute for Occupational Safety and Health (NIOSH),
Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH would like to submit an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners, and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments

(the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which operates in accordance with 42 CFR Part 37, is useful in providing information for protecting the health of and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among U.S. coal miners.

HHS proposes to revise the CWHSP regulations (42 CFR Part 37) by adding a provision to allow NIOSH to suspend or revoke physician B Reader certification for any B Reader suspected of violating the B Reader Code of Ethics or routinely providing chest radiograph classifications in practice that are determined by the CWHSP to be inaccurate. In addition to the B Reader provisions, HHS would also amend existing regulatory text to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis as needed for public health purposes. These changes to 42 CFR 37 have necessitated this revision ICR.

The total estimated annualized burden hours of 11,757 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18) - Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every four years, providing information on how they plan to notify their miners of the opportunity to obtain the medical

examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.

- Radiographic Facility Certification Document (2.11) - X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet including this form which requires approximately 30 minutes for completion.

- Miner Identification Document (2.9) - Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations in relation to the examinations.

- Chest Radiograph Classification Form (2.8) - NIOSH utilizes a radiographic classification system developed by the International Labor Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has at least two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately three minutes per form.

- Physician Application for Certification (2.12) - Physicians taking the B Reader examination are asked to complete

this registration form which provides demographic information as well as information regarding their medical practices. It typically takes the physician about 10 minutes to complete this form.

- Spirometry Facility Certification Document (2.14) - This form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.

- Respiratory Assessment Form (2.13) - This form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately five minutes for this form to be administered to the miner by an employee at the facility.

- Spirometry Results Notification Form (2.15) - This form is used to: collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test results; provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for

processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form.

- Pathologist Invoice - Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only five minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.

- Pathologist Report - Under the NCWAS the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only five minutes of additional burden is estimated for the pathologist's report.

- Consent, Release and History Form (2.6) - This form documents written authorization from the next of kin to perform an autopsy on the deceased miner. A minimum of essential

information is collected regarding the deceased miner including an occupational history and a smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

- DRAFT Authorization for Payment of Autopsy Form (2.XX)
 - Revised 42 CFR Part 37.204 outlines a need for a physician pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202 (a) by completing the Authorization for Payment of Autopsy form and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. This is a new form. It will be completed by the pathologist who intends on conducting an autopsy and the form will collect: demographic information on the deceased miner, characteristics of the miner's pneumoconiosis (if known by the pathologist), demographic and medical licensure information from the requesting pathologist, and proposed payment amount to complete the autopsy in accordance with § 37.203. It is estimated that 15 minutes is required for the pathologist to complete this form.

There are no costs to respondents other than their time. The total estimated burden being requested is 11,757 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Coal Mine Operator	2.10	220	1	30/60	110
Coal Mine Contractor	2.18	160	1	30/60	80
Radiograph Facility Supervisor	2.11	20	1	30/60	10
Coal Miner	2.9	8,500	1	20/60	2833
Coal Miner - Radiograph	No form required	8,500	1	15/60	2125
B Reader Physician	2.8	10	1,760	3/60	880
B Reader Physician Challenge to Disciplinary Action and Appeal of Decertification Decision	No form required	2	4	30/60	4
Physicians taking the B Reader Examination	2.12	220	1	10/60	37
Spirometry Facility Supervisor	2.14	15	1	30/60	8
Spirometry Facility Employee	2.13	8,500	1	5/60	708
Spirometry Technician	2.15	8,500	1	20/60	2833
Coal Miner - Spirometry	No form required	8,500	1	15/60	2125

Pathologist	Invoice- -No standard form	4	1	5/60	1
Pathologist	Patholog y Report -- No standard form	4	1	5/60	1
Next-of-kin for deceased miner	2.6	4	1	15/60	1
Autopsy Prior Authorization	0.1585	4	1	15/60	1
Total					11,757

Jeffrey M. Zirger,

Lead,

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